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REMARKS

Applicants appreciate the notification of allowable subject matter, i.e. that claim 61 is allowable.

Claims 29-32, 40-42, 52, and 58-68 are pending. Claim 69 is added. No new matter has been added by the amendments, support therefore being found in the originally filed claims and specification (e.g., see [0020-0021]). Favorable reconsideration in light of the amendments are remarks which follow a respectfully requested.

1. 35 U.S.C. §102 Rejections

Lee et al (USP 6,306,169)

Claims 29-32, 40-42, 52, 58-59, and 62-68 are rejected under 35 U.S.C. §102(c) over Lee et al (USP 6,306,169).

Applicants respectfully traverse the rejection.

Applicants recite in independent claim 29, materials for in vivo repair of cartilage comprising a cartilage membrane for application over a cartilage free cavity comprising at least one surface part carrying a composition comprising at least one stimulation molecule which induces a signal transduction in chondroblasts/chondrocytes, and a suspension capable of filling the cartilage free cavity.

Applicants recite, in independent claim 52, a kit for cartilage repair comprising a cartilage membrane for application over a cartilage free cavity comprising at least one surface part carrying a composition comprising at least one stimulation molecule which induces a signal transduction in chondroblasts/chondrocytes, and a suspension capable of filling the cartilage free cavity.

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Lee at least does not teach or suggest materials or kits for in vivo repair of cartilage comprising a cartilage membrane for application over a cartilage free cavity comprising at least one surface part carrying a composition comprising at least one stimulation molecule which induces a signal transduction in chondroblasts/chondrocytes, and a suspension capable of filling the cartilage free cavity.

The Office asserts that Lee discloses materials or a kit for the repair of cartilage comprising "a cartilage membrane (first matrix; col. 5, lines 3-11) *for* application over a cavity (Lee's membrane is *capable* of being placed over a cavity; in another light, although may be disclosed to fill an entire cavity, the top portion of the membrane/matrix covers the cavity)" and "a suspension (gelled second matrix with cells; col. 7, lines 5-12, 44-50) *capable* of filling the cavity (the suspension fills the cavity; although the suspension is disclosed to be throughout the matrix/membrane, the membrane is located within the cavity, thus as is the suspension)".

Applicants respectfully submit that Lee describes a structure wherein a first matrix ("membrane") is a porous macrostructure that fills the cartilage free cavity, while a second matrix ("suspension") fills the porous macrostructure of the first matrix. Thus, Lee's matrix is applied within and not over the cavity as set forth in Applicants' claims. Further, Lee's second matrix is not capable of filling the cartilage free cavity because it is the first matrix that fills the cartilage free cavity, while the second matrix merely fills the porous macrostructure of the first matrix.

Thus, claims 29 and 52 are not anticipated by Lee. Claims 30-32, 40-42, 58-59, and 62-68 depend from claims 29 and 52 and, likewise, are not anticipated by Lee. Reconsideration and withdrawal of the rejection is respectfully requested.

Minuth (USP 6,187,053)

Claims 29-32, 40-42, 52, 58-59, 62, 63 and 65-68 are rejected under 35 U.S.C. §102(e) in view of Minuth (USP 6,187,053).

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The Office asserts that Minuth describes materials or a kit for repair of cartilage comprising "a cartilage membrane (8), for application over a cavity" the "membrane (8) comprising a surface part having a composition (10) with a stimulation molecule", and a "suspension (cells 9 in medium) capable of filling the cavity."

Applicants respectfully traverse.

According to Minuth, a membrane 8 is provided with a cell layer 9. On top of the cell layer 9, a coating or layer 10 is provided. This structure is shown in Fig. 5. Thus, the membrane 8 does not comprise a surface part carrying coating or layer 10 ("composition") as set out in Applicants claims. Further, the cells 9 ("suspension"), which are provided on the membrane 8, are coated with the coating or layer 10 and, thus, the cells 9 would not be capable of filling the cavity.

Accordingly, claims 29 and 52 is not anticipated by Minuth. Claims 30-32, 40-42, 58-59, 62, 63, and 66-68 depend from claims 29 and 52 and, likewise, are not anticipated by Minuth. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §103 Rejections

Vibe-Hansen (USP 5,989,269)

Claims 29-32, 40-42, 52, 58-60, and 62-68 are rejected under 35 U.S.C. §102(c) over Vibe-Hansen (USP 5,989,269) or, in the alternative, under 35 U.S.C. §103(a) over Lee et al (USP 6,306,169).

Applicants respectfully traverse.

Vibe-Hansen describes a method, instruments and kit for transplantation comprising a hemostatic barrier, transplanted material (e.g., chondrocyte cells) and a covering patch (see Fig. 3C). The hemostatic barrier may be coated with an organic glue, of which Tisseel is given as an

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example. (Col. 3, line 25-28 and col. 6, lines 45-55). Tisseel is said to contain fibronectin and fibrinogen, among other components. (Col. 6, lines 52-55).

The Office asserts that these materials will inherently induce a signal transduction in chondrocytes.

Applicants respectfully submit that in a previous response, the Office was provided with scientific proof that this assumption is unfounded. Applicant's previous response enclosed excerpts from an article by Mats Brittberg et al. entitled, "The influence of fibrin sealant (Tisseel®) on osteochondral defect repair in the rabbit knee," which was published in the journal *Biomaterials*, Vol. 18 (3) (1997) pp. 235-242. The authors conclude, "...a fibrin adhesive like Tisseel® is not suitable as a scaffold to promote repair of osteochondral defects in the rabbit knee." (emphasis added). Although Tisseel contains fibronectin and fibrinogen, they cannot induce signal transduction in this form as shown by Brittberg et al.

It is well established that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). Rather, "the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); MPEP §2112.

A reference cannot inherently have a function it has been proven not to have, as it has been proven in this case. Therefore, Tisseel is not a "stimulation molecule" as defined by Applicants.

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Accordingly, claims 29 and 52 are not anticipated by Vibe-Hansen. Claims 30-32, 40-42, 58-60, and 62-68 depend from claims 29 and 52 and, likewise, are not anticipated by Vibe-Hansen. Reconsideration and withdrawal of the rejection is respectfully requested.

Lee et al (USP 6,306,169)

As set forth above, Lee describes a first matrix ("membrane") comprising a porous macrostructure that fills the cartilage free cavity, and second matrix ("suspension") that fills the porous macrostructure of the first matrix. Thus, Lee's matrix is applied within and not over the cavity. Further, Lee's second matrix is not capable of filling the cartilage free cavity because it is the first matrix that fills the cartilage free cavity, while the second matrix merely fills the porous macrostructure of the first matrix.

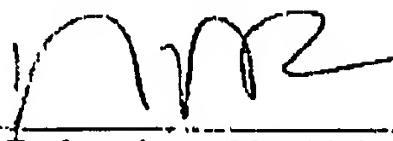
Further, there is no teaching or suggestion to modify Lee to provide a cartilage membrane for application over a cartilage free cavity comprising at least one surface part carrying a composition comprising at least one stimulation molecule which induces a signal transduction in chondroblasts/chondrocytes and a suspension capable of filling the cartilage free cavity. Lee specifically provides a first and second matrix as described so as to form a composite construct that provides particular mechanical properties under compressive loading. Modification of this structure would change the principle of operation of Lee.

Accordingly, claims 29 and 52 are patentable over Lee. Claims 30-32, 40-42, 58-60, and 62-68 depend from claims 29 and 52 and, likewise, are patentable over Lee. Reconsideration and withdrawal of the rejection is respectfully requested.

It is believed the application is in condition for immediate allowance, which action is earnestly solicited.

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Respectfully submitted,



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Peter F. Corless (Reg. No. 33,860)
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, MA 02205
Telephone: 617-439-4444
Facsimile: 617-439-4170

Customer No.: 21874